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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1617	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,344	SAYADA, CHALOM B.	
	Examiner	Art Unit	
	UMAMAHESWARI RAMACHANDRAN	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *31 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the remarks received in the office on 10/31/2008 amending claims 1-6, 15, 17 and 18. Claims 9-11 are withdrawn. Claims 1-8, 12-21 are pending and are being examined on the merits herein.

Response to Remarks/Arguments

The rejection of claims 20, 21 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No.10/651,865 ('865) is withdrawn due to the abandonment of the application 10/651,865. The rejection of claims 1-8, 12-16 under 35 U.S.C. 112, first paragraph is with drawn due to the amendment of claim 1. The 103(a) are rejections are withdrawn due to the amendment of claims. Applicants' arguments regarding the rejections have been fully considered but are moot in view of the new grounds of rejection. Applicants' amendments necessitated the new rejections presented in this office action. Accordingly, the action is made Final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20 and 21are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 36 of the copending Application No. 10/443,351. Although the conflicting claims are not identical, they are not patentably distinct from each other because '351 is drawn to a method of treating bacterial infection by administering rifalazil, which overlaps with the instant claims which are drawn to the method for treating a persistent Chlamydia pneumoniae infection or for reducing Chlamydia pneumoniae replication by administering rifalazil. It would have been obvious to one of ordinary skill in the art, to employ rifalazil disclosed in '351 with reasonable expectation of success in treating Chlamydia pneumoniae infection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 20 and 21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15, 17 and 18 of U.S. Patent No. 7,122,525. Although the conflicting claims are not identical, they are not patentably distinct from each other because '525 is drawn to a method of treating bacterial infection

by administering rifamycin antibiotic of formula XXXIV, which overlaps with the instant claims which are drawn to the method for treating a persistent Chlamydia pneumoniae infection or for reducing Chlamydia pneumoniae replication by administering rifalazil.. It would have been obvious to one of ordinary skill in the art, to employ rifalazil disclosed in '525 with reasonable expectation of success in treating bacterial infection by Chlamydia pneumoniae.

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Claims 1-8, 12-21 rejected under 35 U.S.C. 102(e) as being anticipated by Michaelis et al. (U.S. 2004/0034021, effective filing date June 03 2002).

Michaelis et al. teaches a method for treating or preventing the development of an atherosclerosis-associated disease in a human patient in need thereof, said method comprising the intravenous administration of rifalazil to said patient in an amount

effective to treat or prevent the development of said atherosclerosis-associated disease in said patient (p 17, claim 36). The reference teaches that atherosclerosis-associated disease is coronary artery disease, myocardial infarction, angina pectoris, stroke, cerebral ischemia (p 17, claim 44). The reference states that the patient is typically diagnosed as having the atherosclerosis-associated disease (or being at increased risk of developing the disease) or as having macrophages or foam cells infected with C. pneumoniae prior to the administration of rifalazil (para 0024). The reference further teaches administration of a lipid-lowering agent, statin such as atorvastatin, rosuvastatin, lovastatin, simvastatin, pravastatin, cerivastatin, or fluvastatin (claims 37, 42, 43). The reference also teaches a method of treating a patient diagnosed as having a chronic disease associated with a bacterial infection caused by bacteria capable of establishing a non-multiplying form phase, said method comprising the step of administering rifalazil intravenously to said patient, wherein said administering is for a duration and in an amount effective to treat said patient and the chronic disease is atherosclerosis (p 18, claims 53, 58). The reference teaches rifalazil can be administered by intravenous infusion, wherein between 1 and 48 mg of rifalazil is administered over a period of 4 to 24 hours (para 0032). The reference further teach that the dosage regimen can be repeated daily or for a period of two to fourteen days, or can be repeated every third day for a period of three to fifteen days, or once weekly for a period of three to sixteen weeks (para 0034). The reference also teaches a method of reducing the level of C-reactive protein in a human patient in need thereof administering rifalazil, in an amount effective to reduce the level of C-reactive protein in the patient.

The reference teaches that in one embodiment, the patient has not been diagnosed as having a bacterial infection and in another embodiment, the patient has been diagnosed as having macrophages or foam cells infected with C. pneumoniae. The reference teaches that said method further comprises the step of periodically monitoring the level of C-reactive protein in said patient following administration of said compound. (para 0025, claims 46, 47). Michaelis et al. teaches a method for reducing Chlamydia pneumoniae replication in macrophages or foam cells in a human patient in need thereof, said method comprising the intravenous administration of rifalazil to said patient in an amount effective to reduce Chlamydia pneumoniae replication in macrophages or foam cells in said patient (claim 48). The reference also teaches a method for treating a persistent Chlamydia pneumoniae infection in macrophages or foam cells in a human patient, said method comprising the intravenous administration of rifalazil to said patient in an amount effective to treat said Chlamydia pneumoniae infection in macrophages or foam cells in said patient (claim 49). Thus the reference anticipates the claimed invention of a method of treating atherosclerosis associated disease comprising administering rifalazil. Also, the reference anticipates the claimed inventions of a method of reducing the level of C-reactive protein in a human patient in need thereof administering rifalazil, a method for reducing Chlamydia pneumoniae replication in macrophages or foam cells in a human patient in need thereof, said method comprising the administration of rifalazil, a method for treating a persistent Chlamydia pneumoniae infection in macrophages or foam cells in a human patient comprising administration of rifalazil to said patient.

Claims 1-8, 12-21 rejected under 35 U.S.C. 102(e) as being anticipated by Cabana et al. (U.S. 2004/0157840, effective filing date Sep 23 2002).

Cabana et al. teaches a method for treating or preventing the development of an atherosclerosis-associated disease in a patient in need thereof, said method comprising administering rifalazil to said patient in an amount effective to treat or prevent the development of said atherosclerosis-associated disease in said patient, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil. The reference further teaches administration of a lipid-lowering agent, statin that includes atorvastatin, rosuvastatin, lovastatin, simvastatin, pravastatin, cerivastatin, or fluvastatin (Claims 30, 31, 36, 37). The reference further teaches that atherosclerosis-associated disease is coronary artery disease, myocardial infarction, angina pectoris, stroke, cerebral ischemia, intermittent claudication, gangrene, mesenteric ischemia, temporal arteritis, or renal artery stenosis (Claim 38). The reference teaches a method of reducing the level of C-reactive protein in a patient identified as having increased levels of C-reactive protein, said method comprising administering rifalazil to said patient in an amount sufficient to reduce the level of C-reactive protein, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil and also said method further comprises the step of periodically monitoring the level of C-reactive protein in said patient following administration of said compound (claims 40, 41). Cabana et al. teaches in the reference a method for reducing Chlamydia pneumoniae replication in macrophages or foam cells in a patient in need thereof, said method comprising administering rifalazil to said patient in an amount effective to reduce

Chlamydia pneumoniae replication in macrophages or foam cells in said patient, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil and a method for treating a persistent Chlamydia pneumoniae infection in macrophages or foam cells in a patient, said method comprising administering rifalazil to said patient in an amount effective to treat said Chlamydia pneumoniae infection in macrophages or foam cells in said patient, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil (claims 42, 43). The reference teaches low-dosage regimen for the administration of rifalazil to a patient, wherein between 0.01 and 10 mg of rifalazil is administered over a period of four to fourteen days (para 0036). The reference also teaches that in a method of treating atherosclerosis-associated disease in a human patient, the patient is typically diagnosed as having the atherosclerosis-associated disease (para 0022).The reference also teaches reducing the level of C-reactive protein in a human patient who has not been diagnosed as having a bacterial infection (para 0023).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Rose et al. (US 6,566,354).

Rose et al. discloses a method for the treatment of bacterial infection caused by Chlamydia pneumoniae by administering to a patient 1-100 mg of rifalazil, which belongs to a class of antibiotics called ansamycins, once or twice a week. See abstract. It is taught that Chlamydia pneumoniae, bacteria whose life cycle includes a persistent, non-multiplying phase, causes respiratory infections, such as pneumonia, bronchitis, pharyngitis and sinusitis. See column 1, lines 44-53. It is also taught that rifalazil has same or better activity than either rifabutin or rifampin, which also belong to the same class. Thus Rose et al. anticipates the method of treating persistent bacterial infection and by treating the infection it teaches a method of reducing the Chlamydia pneumoniae replication in macrophages or foam cells comprising administering a rifamycin rifalazil in a patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. (US 6,566,354), in view of Baumgart et al (WO 00/01378) and Kuo et al. (Infectious disease and therapy, 21, 1997, 317-321) in view of Ullah et al. (U.S. 6,235,311).

Rose et al. discloses a method for the treatment of bacterial infection caused by Chlamydia pneumoniae by administering to a patient 1-100 mg of rifalazil, which belongs to a class of antibiotics called ansamycins, once or twice a week. See abstract. It is taught that Chlamydia pneumoniae, a bacteria whose life cycle includes a persistent, non-multiplying phase, causes respiratory infections, such as pneumonia, bronchitis, pharyngitis and sinusitis. See column 1, lines 44-53. It is also taught that rifalazil has same or better activity than either rifabutin or rifampin, which also belong to the same class. See column 2, lines 4-14. Rose et al. teaches a dosage of 25-50 mg/week method can be administered to treat bacterial infection (claim 9).

Rose et al. does not specifically teach the employment of rifalazil in the method of treating atherosclerosis associated disease.

Baumgart et al teach methods and pharmaceutical compositions for the treatment or prevention of conditions and vascular diseases associated with infection of Chlamydia species or similar susceptible microorganisms in a patient (see Abstract). The reference teach C.pneumoniae has been identified in atherosclerotic plaque and incriminated in vascular disease that it is an obligate intracellular pathogen that grows within macrophages and epithelial cells (p1, lines 5-19). The reference further teaches

that Chlamydia infection is associated with disorders such as atherosclerotic vascular disease affecting coronary arteries, myocardial infarction, aortic vascular disease, renovascular and glomerular disease etc (p 5, lines 7-12).

Kuo et al. teaches that C. pneumoniae is associated with chronic diseases, such as atherosclerosis, and coronary heart disease. Kuo et al. also teach that KRM-1648 (known as rifalazil) has potent activity against C. pneumoniae. See pages 317-318; page 321.

It would have been obvious to a person of ordinary skill in the art at the time of invention to administer rifalazil in the method of treating atherosclerosis associated disease because 1) Rose et al. teach that rifalazil is known to treat infections caused by Chlamydia pneumoniae, 2) Kuo et al. teaches that C. pneumoniae is associated with chronic diseases, such as atherosclerosis. 3) Baumgart et al reference teaches that Chlamydia infection is associated with disorders such as atherosclerotic vascular disease affecting coronary arteries, myocardial infarction, aortic vascular disease, renovascular and glomerular disease etc. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to administer rifalazil with reasonable expectation of success of treating atherosclerosis associated disease by eliminating bacterial infection caused by Chlamydia pneumoniae, since Chlamydia pneumoniae is associated with atherosclerosis associated disorders such as myocardial infarction, aortic vascular disease etc.

The references do not teach in the composition a second therapeutic agent, a lipid-lowering agent such as statin in a method of treatment of atherosclerosis associated disease.

Ullah et al. teach a pharmaceutical composition comprising a statin such as lovastatin, simvastatin, cerivastatin, a cholesterol lowering agent for use in lowering cholesterol and reducing risk of a myocardial infarction, and to a method for lowering cholesterol and reducing risk of a myocardial infarction or treating atherosclerosis employing such composition (see Abstract, col. 1, line 60, col.5, lines 37-39).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have added a second therapeutic agent such as a lipid lowering agent in a method of treatment of atherosclerosis associated disorders because Ullah et al. teach that statins are useful in lowering cholesterol and reducing risk of a myocardial infarction or treating atherosclerosis. One of ordinary skill in the art would have been motivated to add a second therapeutic agent such as a lipid lowering agent in a method of treatment of atherosclerosis associated disorders along with rifalazil in expectation of success in achieving therapeutic benefits because statins are shown to reduce the risk of myocardial infarction and rifalazil has been shown to be useful in treating bacterial infection caused by Chlamydia pneumoniae, and Chlamydia pneumoniae is associated with atherosclerosis associated disorders such as myocardial infarction, aortic vascular disease etc.

The references do not teach the dosage treatment of rifalazil as claimed in claim 6 of the instant application.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have a applied dosage treatment of rifalazil as claimed in claims 6 of the instant application because Rose et al. teaches safety dosage of 1-100 mg of rifalazil in a method of treating bacterial infections and also teaches dosages for weekly treatments. It would have been obvious to one of ordinary skill in the art to administer an initial dose for one to for one to seven consecutive days, followed by a maintenance dose because dosage regimen is clearly a result effective parameter that can be routinely optimized based on the patient's age, weight, disease condition etc. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount and dosage therapy treatment would have been obvious at the time of applicant's invention.

The reference does not teach that the patient has been diagnosed with atherosclerosis associated condition prior to administering rifalazil. It would have been obvious to one of ordinary skill in the art at the time of the invention that patient diagnosed with atherosclerosis associated condition prior to administering rifalazil can be administered rifalazil because the secondary reference Kuo et al. and Baumgaurt clearly teaches that C. pneumoniae is associated with chronic diseases, such as atherosclerosis, atherosclerotic vascular disease affecting coronary arteries, myocardial infarction etc. One having ordinary skill in the art would have been motivated to

administer rifalazil to patients with atherosclerosis associated condition because rifalazil is useful in treating C. pneumoniae conditions and C. pneumoniae is associated with conditions like myocardial infarction.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. (US 6,566,354), in view of Baumgart et al (WO 00/01378) and Kuo et al. (Infectious disease and therapy, 21, 1997, 317-321) in view of Ullah et al. (U.S. 6,235,311) as applied to claims 1-8, 12-15 above and further in view of Michaelis et al. (U.S. 2004/0034021, effective filing date June 03 2002).

Rose, Baumgart, Ullah and Kuo et al.'s teachings discussed as above.

The references do not teach a method of reducing the c-reactive protein o monitoring the level of c-reactive protein administering rifalazil.

Michaelis et al. teaches as discussed above, teaches a method of reducing the level of C-reactive protein in a human patient in need thereof administering rifalazil, in an amount effective to reduce the level of C-reactive protein in the patient. The reference teaches that in one embodiment, the patient has not been diagnosed as having a bacterial infection and in another embodiment, the patient has been diagnosed as having macrophages or foam cells infected with C. pneumoniae. The reference teaches that said method further comprises the step of periodically monitoring the level of C-reactive protein in said patient following administration of said compound. (para 0025, claims 46, 47).

It would have been obvious to one ordinary skill in the art at the time of the invention to use rifalazil in a method a reducing c-reactive protein from the teachings of

Michaelis et al. One having ordinary skill in the art at the time of the invention would have been motivated to do so in expectation of success.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al. (US 6,566,354), in view of Baumgart et al (WO 00/01378) and Kuo et al. (Infectious disease and therapy, 21, 1997, 317-321) in view of Ullah et al. (U.S. 6,235,311) as applied to claims 1-8, 12-15 above and further in view of Ridker et al. (U.S. 6,040, 147).

Rose, Baumgart, Ullah and Kuo et al.'s teachings discussed as above.

The references do not teach a method of reducing the c-reactive protein o monitoring the level of c-reactive protein administering rifalazil.

Ridker et al. teaches C-reactive protein is a marker for underlying systemic inflammation, elevated levels of C-reactive protein have been described among patients with acute ischemia or myocardial infarction, and predict episodes of recurrent ischemia among those hospitalized with unstable angina and plasma concentration of C-reactive protein is associated with risk of myocardial infarction among unhealthy patients, such as those with symptomatic angina pectoris.

It would have been obvious to one ordinary skill in the art at the time of the invention to use rifalazil in a method a reducing c-reactive protein from the prior art teachings because 1) Rose et al. teach that rifalazil is known to treat infections caused by Chlamydia pneumoniae, 2) Kuo et al. teaches that C. pneumoniae is associated with chronic diseases, such as atherosclerosis. 3) Baumgart et al reference teaches that Chlamydia infection is associated with disorders such as atherosclerotic vascular

disease affecting coronary arteries, myocardial infarction, aortic vascular disease, renovascular and glomerular disease etc. 4) Ridker teaches C-reactive proteins are elevated among patients with myocardial infarction. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention that upon administration of rifalazil the infections associated with conditions like atherosclerosis is treated and treating the systemic inflammation would reduce the levels of c-reactive protein. The reference does not explicitly teach that the c-reactive protein levels are periodically monitored. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have monitored the c-reactive protein levels periodically because Ridker et al. teaches the c-reactive protein as a marker for systemic inflammation. One having ordinary skill in the art at the time of the invention would have been motivated to monitor the c-reactive protein levels periodically for general wellness and upkeep of the patient's health as it is a diagnostic marker for the coronary disease.

Conclusion

No claims are allowed.

Applicants' amendments necessitated the new rejections presented in this office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617